



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,249	11/10/2000	Alan H. Lazarus	701826-050990	3430

7590 09/11/2003  
Nixon Peabody LLP  
101 Federal Street  
Boston, MA 02110

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 09/11/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/709,249

Applicant(s)  
Lazarus et al.

Examiner  
G.R. Ewoldt, Ph.D.

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 30, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

### DETAILED ACTION

1. Claims 1-5 are pending and being acted upon.
2. In view of Applicant's amendment and response, filed 6/30/03, the previous rejections under the second paragraph of 35 U.S.C. 112 and the first paragraph of 35 U.S.C. 112 (for lack of deposit and recitation of "HLA"), have been withdrawn.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1-5 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for inhibiting an HLA alloimmune response to platelet transfusion comprising presensitizing platelets with a monoclonal antibody, or F(ab)<sub>2</sub> fragment thereof, against HLA Class I,

does not reasonably provide enablement for:

a method for inhibiting an HLA alloimmune response to platelet transfusion comprising presensitizing platelets with an antigen binding fragment of a monoclonal antibody against HLA Class I,, for the reasons of record as set forth in Paper No. 14, mailed 4/03/03.
- Applicant has amended antibody "portion" to now recite "an antigen binding fragment" (of an antibody). This amendment however, does not address the requirement that the antibody be able to crosslink. Accordingly, the rejection has been maintained.
5. The following is a new ground of rejection necessitated by Applicant's amendment.
6. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for inhibiting an HLA alloimmune response to platelet transfusion comprising presensitizing platelets with a monoclonal antibody, or F(ab)<sub>2</sub> fragment thereof, against HLA Class I,

does not reasonably provide enablement for:

a method for inhibiting an HLA alloimmune response to platelet transfusion comprising presensitizing platelets with monoclonal antibody W6/32, L368, or MA2.1.

Applicant has submitted ATCC catalog descriptions of monoclonal antibodies W6/32, L368, or MA2.1. Said descriptions specifically state, "ATCC products are intended for laboratory use only. They are not intended for use in humans." The method of the instant claim recites the pretreating of platelets with the aforementioned antibodies followed by the administration of said platelets to a human (only humans display HLA alloimmune responses). Note that neither the claim nor the specification recite/disclose that the antibodies are removed from the platelets before administration. Accordingly, Applicant has supplied a teaching indicating that antibodies W6/32, L368, and MA2.1. cannot be used in the claimed method, i.e., the claimed method is not enabled.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or

Serial No. 09/709,249  
Art Unit 1644

4

relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "G.R. Ewoldt". The signature is stylized with a large, sweeping initial "G" and a distinct "Ewoldt" following.

G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600  
September 10, 2003